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Clinical Trial Application submitted for Phase I study of ONO-7268MX1, peptide-cocktail vaccine  
for hepatocellular carcinoma

Ono Pharmaceutical Co., Ltd (referred to as “Ono”, hereafter) today announced that Ono has submitted Clinical Trial Application for Phase I study for ONO-7268MX1, a peptide-cocktail vaccine for hepatocellular carcinoma, which was in-licensed from OncoTherapy Science Inc.

The aim of this clinical study is to evaluate safety and immune response when the administration of ONO-7268MX1, a peptide-cocktail vaccine to hepatocellular carcinoma patients who are refractory or intolerant to standard therapy.

Hepatocellular carcinoma accounts for 90% of primary hepatic cancer in Japan and approximately 30 thousands patients reportedly die annually. Meanwhile, as treatments for hepatocellular carcinoma, surgical treatments such as hepatic resection, radiofrequency ablation and/or percutaneous ethanol injection are performed as well as chemotherapy and/or radiotherapy, however the prognosis is poor and novel treatment has been desired.

ONO-7268MX1, a peptide-cocktail vaccine preparation for hepatocellular carcinoma, is a cocktail vaccine with active ingredient of epitope peptides derived from multiple oncoantigens specifically expressed in hepatocellular carcinoma, and is strongly expected to show anti-tumor activity by inducing hepatocellular carcinoma-specific cytotoxic T cell. This clinical study is going to evaluate the safety of ONO-7268MX1 as well as the immune response induced by the vaccine and will lead to the subsequent phase of the clinical study.